13-1564

No.

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### In the Supreme Court of the United States

OCTOBER TERM, 1983

WILLIAM D. RUCKELSHAUS, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, APPELLANT

v.

Union Carbide Agricultural Products Co., ET al.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

#### JURISDICTONAL STATEMENT

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#### QUESTIONS PRESENTED

- 1. Whether a constitutional challenge to the data compensation and arbitration scheme of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136a(c)(1)(D)(ii), was ripe for review in the absence of an allegation or showing that any of the plaintiffs had participated in and were harmed by an arbitration under the statute.
- 2. Whether, if we assume the issue is ripe, FIFRA's data compensation and arbitration provisions violate Article III of the United States Constitution because the awards made by the arbitrators selected under the statute are subject to review by an Article III court only on a showing of "fraud, misrepresentation or other misconduct," 7 U.S.C. 136a(c)(1)(D)(ii).
- 3. Whether, if we assume the issue is ripe and these provisions violate Article III, the plaintiffs were entitled to a judgment invalidating the entire scheme for consideration of previously submitted data rather than a judgment striking the limitation on judicial review.

#### PARTIES TO THE PROCEEDING

In addition to those named in the caption, the parties are: Abbott Laboratories, Ciba-Geigy Corporation, E.I. duPont De Nemours Company, Rhone-Poulenc, Inc., Rohm and Haas Company, Uniroyal, Inc., Zoecon Corporation, Stauffer Chemical Corporation, FMC Corporation, and Velsicol Chemical Corporation. The following companies, originally parties to this action, were dismissed prior to final judgment: Ralston Purina Company, Salisbury Laboratories, Inc., Sandoz, Inc. and Upjohn Company.

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#### JURISDICTIONAL STATEMENT

#### OPINION BELOW

The opinion of the district court (App., infra, 1a-14a) is reported at 571 F. Supp. 117.

#### JURISDICTION

The judgment of the district court (App., infra, 15a-16a) was entered on November 30, 1983. The Administrator of the Environmental Protection Agency filed a notice of appeal to this Court on December 21, 1983 (App., infra, 17a-18a). On February 13, 1984, Justice Marshall extended the time for docketing the appeal to March 20, 1984. The jurisdiction of this Court is invoked under 28 U.S.C. 1252.

## CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article III, Section 1, of the United States Constitution and the relevant portions of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq., are reprinted in App., infra, 19a-22a.

#### STATEMENT

1. The court below declared unconstitutional a key provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seg., the federal legislation regulating the marketing and use of pesticides. 1 Under FIFRA, persons seeking to market a pesticide product in the United States first must obtain a registration from the Environmental Protection Agency (EPA), 7 U.S.C. 136a(a). Before issuing the registration, the Administrator of EPA must determine, inter alia, that the pesticide's use will not cause unreasonable adverse effects on the environment, taking into account the benefits as well as the risks to humans or the environment. 7 U.S.C. 136(bb). 136a(c)(5)(C)-(D). The Administrator bases this determination, in part, on test data submitted or cited by the applicant for registration, data that generally include information on the chemical nature and structure of the pesticide as well as test results on the potential dangers of the product. Section 3(c)(1)(D) of FIFRA permits EPA to consider certain categories of health and safety data submitted by one applicant in support of the application of another company. 7 U.S.C. 136a(c)(1)(D). That

<sup>&</sup>lt;sup>1</sup> A similar challenge to this statute is currently pending in this Court in *Ruckelshaus* v. *Monsanto Co.*, No. 83-196 (argued Feb. 27, 1984).

Section also provides that the later applicant, in order to cite the data, must offer to compensate the original submitter; if the parties cannot agree on the amount of compensation, either may initiate binding arbitration proceedings. The decision of the arbitrator may be reviewed only upon a showing of "fraud, misrepresentation, or other misconduct" (*ibid.*).

In the Federal Pesticide Act of 1978, Pub. L. No. 95-396, 92 Stat. 819 (1978 Amendments), Congress modified FIFRA's registration scheme 2 in order to promote competition and to eliminate needless duplicative testing. Under the 1978 Amendments, applicants are granted a 10-year period of exclusive use for data on new active ingredients contained in pesticides registered after September 30, 1978. § 3(c)(1)(D)(i), 7 U.S.C. 136a(c)(1)(D)(i). All other data submitted after December 31, 1969, may be cited and considered in support of another application for 15 years following the original submission if the applicant offers to compensate the original submitter. § 3(c)(1)(D)(ii), 7 U.S.C. 136a(c)(1)(D)(ii). Data that do not qualify for either the 10-year period of exclusive use or the 15-year period of compensation may be considered by EPA without limitation. § 3(e)(1)(D)(iii), 7 U.S.C. 136a(e)(1)(D)(iii).

Congress also modified the compensation provisions, changing significantly EPA's role in the scheme. Unlike the prior statutory regimen, in which EPA decided the amount and terms of compensation when the data submitter and the subsequent applicant could not agree,

<sup>&</sup>lt;sup>2</sup> The prior statutory history is discussed in our brief in *Monsanto* (at 3-11) No. 83-196. A copy of that brief is being served on counsel for appellees.

the revised statute provides that either party may initiate arbitration proceedings by asking the Federal Mediation and Conciliation Service to designate an arbitrator. § 3(c)(1)(D)(ii), 7 U.S.C. 136(c)(1)(D)(ii). The statute further provides that the "findings and determination of the arbitrator shall be final and conclusive" and not subject to judicial review "except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator" (ibid.).3

2. Several large pesticide firms brought this action in 1976 in the United States District Court for the Southern District of New York, challenging the constitutionality of the disclosure provisions of FIFRA, as amended in 1972 and 1975. Following the 1978 Amendments, appellees amended their complaint to allege that both the data consideration and data disclosure provisions took their property in violation of the Fifth Amendment and deprived them of their property without due process of law. The district court granted appellees' motion for a preliminary injunction with respect to all data submitted prior to the enactment of the 1978 Amendments, Amchem Products, Inc. v. Costle, 481 F. Supp. 195 (S.D.N.Y. 1979). The Second Circuit reversed, however, concluding that appellees had failed to show a likelihood of success on the merits, and this Court denied a petition for a writ of certiorari. Union

<sup>&</sup>lt;sup>3</sup> Section 3(c)(1)(D)(ii) also provides for sanctions for parties who do not cooperate with the arbitration scheme. If an applicant fails to comply with the terms of a compensation agreement or an arbitration award, its registration is subject to cancellation; if a data submitter fails to participate or otherwise comply, it forfeits its right to compensation (7 U.S.C. 136(c)(1)(D)(ii)).

Carbide Agricultural Products Co. v. Costle, 632 F.2d 1014 (1980), cert. denied, 450 U.S. 996 (1981).

Following that round of litigation, appellees stipulated to dismissal with prejudice of their taking claims and their due process claims as to the data consideration provisions. Thus, two contentions remained: (1) that the disclosure provisions, as applied to data submitted prior to 1978, violated due process, and (2) that the arbitration and compensation provisions were an unconstitutional delegation of legislative authority. After this Court's decision in Northern Pipeline Construction Co. v. Marathon Pipe Line Co., 458 U.S. 50 (1982), appellees maintained that the arbitration and compensation scheme violated Article III of the United States Constitution because the statute impermissibly assigned judicial functions to the arbitrators and limited judicial review.

The district court granted appellees' motion for summary judgment on their Article III claim (App., infra, 15a). The court first rejected the government's contention that any challenge to the compensation and arbitration scheme was not ripe for review until a party had suffered harm from the results of a specific arbitration (App., infra, 10a n.2). In the court's view, there was no advantage in delaying resolution of the issue; the mere "statutory compulsion to seek relief through arbitration" was sufficient to create a concrete case or controversy (id. at 11a n.2). On the merits, the court agreed with appellees' contention (id. at 13a) that the arbitra-

<sup>&</sup>lt;sup>4</sup> The court rejected appellees' due process claim against the retroactive application of the disclosure provisions (App., infra, 9a).

tion scheme "impermissibly intrudes on areas of decisionmaking constitutionally entrusted to the judiciary," relying on this Court's decision in Northern Pipeline Construction Co. v. Marathon Pipe Line Co., supra. Because the statute barred Article III courts from reviewing the arbitrator's decision except for "fraud, misrepresentation, or other misconduct," there was, in the court's view, an "absolute assignment of power" to the arbitrators that violated Article III (App., infra, 13a).

On the basis of this holding, the district court entered a broad injunction (App., infra, 15a-16a). Rather than striking down merely the limitation on judicial review of the arbitrator's decision, the court declared the entire compensation and arbitration scheme unconstitutional (ibid.). Further, the court enjoined the Administrator from "permitting or implementing any use of data where the submitter's compensation is to be determined under the said section 3(c)(1)(D)," save when the original data submitter consents to the use of such data (ibid.). As a result, the effect of this order is to invalidate all of Section 3(c)(1)(D)(ii), providing for the consideration of data in the 15-year period following their submission.

#### THE QUESTIONS PRESENTED ARE SUBSTANTIAL

The district court has enjoined enforcement of a key provision of FIFRA that effectuates Congress's express intent that the pesticide registration program become more efficient and that competition in the industry be increased. Because the court apparently viewed the arbitration procedures as an integral part of the data consideration provisions, the judgment prevents EPA from granting registrations based on previously

submitted data without the permission of the firm that submitted the data. It thus invalidates the heart of the comprehensive scheme created by Congress in its effort to weigh the need for increased competition and the need for innovation in the pesticide industry. The injunction here is nearly as broad as that entered in *Monsanto*. Here, as in *Monsanto*, if the decision is allowed to stand, Congress's desire to encourage competition in the pesticide industry and avoid unnecessary duplication of testing will be thwarted.

All the issues presented here are also under consideration in Monsanto. In that case, we have appealed from a district court judgment declaring that FIFRA's data disclosure and consideration provisions take Monsanto's property in violation of the Fifth Amendment (83-196 J.S. App. 41a). The district court in Monsanto also held that the compensation and arbitration scheme violated Article III (id. at 34a-35a, 41a). The decision below is no more correct than the opinion under review in Monsanto. First, the court erroneously held that the challenge to the arbitration scheme was ripe for review, despite the fact that no concrete case involving the results of an arbitration was presented. Second, the district court's decision on the merits ignores this Court's decisions approving the use of mandatory arbitration schemes that afford limited judicial review. Third, the relief is far broader than the holding required, and has the effect of invalidating not only the arbitration provisions, but also a critical part of the overall regulatory scheme. Consequently, this case should be held pending the decision in Monsanto and disposed of in accordance with that decision.

1. The challenge to the constitutionality of the arbitration and compensation scheme was premature since none of the appellees alleged or established that it had been injured by an actual arbitration under the statute. In these circumstances, the issue was not ripe for review. Ripeness is a threshold element of Article III's requirement of a case or controversy. See Duke Power Co. v. Carolina Environmental Study Group, Inc., 438 U.S. 59, 81 (1978); Regional Rail Reorganization Act Cases, 419 U.S. 102, 138 (1974). Accordingly, federal courts are without jurisdiction to adjudicate hypothetical disagreements or abstract claims before action has been taken that has a concrete effect on an aggrieved party. Abbott Laboratories v. Gardner, 387 U.S. 136, 148-149 (1967); Toilet Goods Association v. Gardner, 387 U.S. 158, 164 (1967). To determine if a question is ripe for review, the Court must consider the "fitness of the issues for judicial decision" and weigh that consideration against "the hardship to the parties of withholding court consideration." Abbott Laboratories v. Gardner. 387 U.S. at 149.

In this case, the asserted claims of unconstitutionality are premature in the absence of a specific arbitration award to review. The statute itself inflicts no harm on the plaintiffs, and the likelihood of injury is wholly speculative at present since appellees would suffer concrete injury only after a series of discrete, independent events. First, a company must apply for a registration based on data submitted by one of the appellees and compensable under Section 3(c)(1)(D). Next, EPA must decide to grant the registration, the company must offer to compensate the data submitter, the parties must disagree, and arbitration must be initiated and com-

pleted with an award. At any stage, the appellees' statutory right to compensation may not mature or may be fully satisfied. No immediate injury is caused by enactment of the statute; the many possible contingencies show that the claimed injury is entirely speculative. See *Toilet Goods Association* v. *Gardner*, 387 U.S. at 163-164.

Precisely the same considerations led this Court to dismiss as premature a similar attack on a statutory requirement for binding arbitration in *Babbitt* v. *United Farm Workers Nat'l Union*, 442 U.S. 289, 304-305 (1979). In that case, an Arizona statute required binding arbitration of a labor dispute between farm workers and agricultural employers if there was a strike and if the employer responded by obtaining a temporary restraining order enjoining the strike. This provision was alleged to violate due process and the constitutional right to a jury trial. The Court held that so long as there was a possibility of settling such disputes through

<sup>&</sup>lt;sup>5</sup> One of the appellees, Stauffer Chemical Corporation, had, by the time of decision below, in fact been a party to an arbitration under the statute. The arbitrator awarded to Stauffer not only a share of the data development costs but also compensation based on the subsequent registrant's product sales. But there was no allegation in the present case that Stauffer had been injured by the arbitration process nor did the complaint here seek review of the award. Rather, the other party to the arbitration, PPG Industries, has attacked that award as excessive and has claimed that Section 3(c)(1)(D) is unconstitutional under the Due Process Clause, the Taking Clause and Article III. PPG Industries, Inc. v. Stauffer Chemical Co., Civil Action No. 83-1941 (D.D.C. filed July 7, 1983). Stauffer Chemical Corporation, an appellee in the instant case, has counterclaimed in that action for enforcement of the award, and has crossclaimed in the alternative against EPA as a defendant for a declaration that the statute violates Article III and the Fifth Amendment.

negotiation and without the need to invoke the challenged arbitration procedures, "any ruling on the compulsory arbitration provision would be wholly advisory." 442 U.S. at 305.

In addition, there is no hardship in withholding judicial review at this time. If and when any of the appellees receives an award that, in its view, is inadequate and illegal, the company may bring an action to challenge the award and present its constitutional claims in that proceeding.<sup>6</sup>

Precisely the same issue is presented in *Monsanto*. There, as here, the plaintiff had not alleged any injury from a specific arbitration. Thus, the government argued (83-196 Gov't Br., at 44-47) that the questions were premature and Monsanto has conceded in its brief that they were not ripe for review (83-196 Monsanto Br., at 40 n.56). No different result should obtain here.

2. Even if this claim were ripe for review, the district court erred on the merits. Binding arbitration of statutorily created entitlements does not offend any requirement of procedural due process. Hardware Dealers Mutual Fire Insurance Co. v. Glidden Co., 284 U.S. 151, 157-158 (1931) (state statute mandating arbitration of the amount of loss under insurance policy). See Crane v. Hahlo, 258 U.S. 142 (1922) (damage awards for municipal construction work reviewable only for jurisdictional defects, fraud, or willful misconduct). See also Andrews v. Louisville & N. R.R., 406 U.S.

As noted above, see note 5, supra, one such proceeding is currently pending in the United States District Court for the District of Columbia. It was not brought by Stauffer, an appellee here, but by the losing party in the arbitration, PPG Industries.

320 (1972); Switchmen's Union v. National Mediation Board, 320 U.S. 297 (1943); Ludwig Honold Mfg. Co. v. Fletcher, 405 F.2d 1123 (3d Cir. 1969); Edwards v. St. Louis-S.F.R.R., 361 F.2d 946 (7th Cir. 1966).

Contrary to the district court's holding, FIFRA does not offend Article III by assigning the resolution of a compensation dispute to an arbitrator whose decision is subject to limited judicial review. This Court has upheld laws that "withdrfelw judicial review of administrative determinations in numerous cases involving the statutory rights of private parties." South Carolina v. Katzenbach, 383 U.S. 301, 333 (1966). See Switchmen's Union v. National Mediation Board, 320 U.S. at 300-301, 303. Moreover, this Court's recent decision in Northern Pipeline Construction Co. v. Marathon Pipe Line Co., 458 U.S. 50 (1982), is not to the contrary. The vice of the 1978 Bankruptcy Act was the assignment to the bankruptcy courts of the authority to adjudicate traditional common law rights (id. at 81-86); the challenged provisions of FIFRA deal only with a statutorily-created right of recent vintage. Indeed, the plurality in Northern Pipeline reaffirmed Congress's constitutional authority to proceed in this manner (458 U.S. at 83) (footnote omitted)):

[W]hen Congress creates a statutory right, it clearly has the discretion, in defining that right, to create presumptions, or assign burdens of proof, or prescribe remedies; it may also provide that persons seeking to vindicate that right must do so before particularized tribunals created to perform the specialized adjudicative tasks related to that right.

Thus, the court below erred in relying on Northern Pipeline to strike down the arbitration provision.

3. Finally, even if the statutory provision had correctly been found to violate Article III, that conclusion would not justify enjoining the operation of Section 3(c)(1)(D)(ii) in its entirety. On the contrary, the only appropriate relief would be to strike down the limitation on review by an Article III court, since there can be no doubt that the scheme would be constitutional so long as full judicial review was available. See Northern Pipeline, 458 U.S. at 83; Crowell v. Benson, 285 U.S. 22, 50 (1932). See also United States v. Raddatz, 447 U.S. 667, 682-683 (1980); St. Joseph Stock Yards Co. v. United States, 298 U.S. 38, 53 (1936).

The district court's apparent conclusion that the limitation on judicial review was integral to the operation of the data consideration, compensation and arbitration scheme cannot be sustained. Whether a statute or any of its provisions should be viewed as inseparable is a matter of Congressional intent. Buckley v. Valeo, 424 U.S. 1, 108-109 (1976); Tilton v. Richardson, 403 U.S. 672, 682-684 (1971); Electric Bond & Share Co. v. SEC, 303 U.S. 419, 434 (1938). Here, Congress has plainly spoken. The statute provides that the invalidity of "any provision \* \* \* or the application thereof \* \* \* shall not affect other provisions or applications" (7 U.S.C. 136x). The achievement of the primary purpose of Section 3(c)(1)(D)(ii), to permit consideration of previously-submitted data and to provide a compensation mechanism for that use of the data, is not dependent on the limitation on judicial review, and there is nothing in the legislative history to suggest that Congress would have failed to enact the provision without such a limitation. The district court, therefore, failed to

fulfill its duty "to save and not to destroy" the remaining portions of the statute. Tilton v. Richardson. 403 U.S. at 684, (quoting NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1, 30 (1937)).

#### CONCLUSION

This case should be held pending the decision in Ruckelshaus v. Monsanto Co., No. 83-196, and disposed of in accordance with that decision.

Respectfully submitted.

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Environmental Protection Agency

**MARCH 1984** 

# APPENDIX A UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

76 Civ. 2913 (RO)

Union Carbide Agricultural Products Co., Inc., Et al., Plaintiffs,

against

WILIAM D. RUCKLESHAUS, AS ADMINISTRATOR OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGEN-CY, ET AL., DEFENDANTS

July 28, 1983

#### OPINION AND ORDER

OWEN, District Judge

This action arises out of a challenge to the constitutionality of certain aspects of the 1978 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. Specifically, plaintiffs object to the requirement that they disclose their testing data to the public (the "disclosure" provisions) and a second requirement that allows competitors to use such data in support of their own pesticide registrations (the "use" provisions). Defendant is the administrator of the United States Environmental Protection Agency (the "EPA"). The parties are presently before me on cross-motions for summary judgment. Before I turn to the merits, a review of the statutory history is appropriate.

In 1947, Congress enacted the forerunner of today's FIFRA. At inception, the statute simply required the developer or manufacturer of a pesticide to register its product with the Secretary of Agriculture prior to

introducing it into the marketplace. The registration process itself was relatively straightforward. An applicant was required to file its name and address, the name of the pesticide to be registered, a complete copy of the labeling and a statement of the claims made for it, including directions for use, and, if requested by the Secretary, a full description of the tests made and the results upon which any claims were based. The Secretary was also vested with the power to require an applicant to submit the complete formula of its pesticide. If it appeared that its composition was such as to warrant the proposed claims made for it and if it otherwise conformed with the requirements of FIFRA, after reviewing the data submitted the Secretary registered the pesticide. If the Secretary was dissatisfied with the application, the applicant would be provided with notice and an opportunity to correct its deficiencies.

FIFRA was substantially revised in 1972:

as a response to growing public concern about public health and ecological effects of pesticides. The new FIFRA provided for a more complete registration process and stronger enforcement measures, and heralded a policy of thorough scientific analysis of pesticide chemicals before making them available to the public. Now ... not only does an applicant for registration have to show his pesticide's composition is such as to warrant the proposed claims made for it and that its labeling and other submitted materials comply with the Act before he may obtain a registration but the EPA must also determine that the pesticide will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, it will not generally cause adverse effects on the environment.

Mobay Chemical Corp. v. Costle, 517 F.Supp. 254, 258 (W.D.Pa. 1981) aff'd in part sub. nom. Mobay Chemical Corp. v. Gorsuch, 682 F.2d 419 (3rd Cir. 1982).

The 1972 amendments still required persons applying to register pesticides to submit extensive testing data in support of their registrations but allowed them to retain certain proprietary rights in their data even after submission. To this end, former section 10(a) permitted data submitters to designate portions of their data as either trade secrets or commercial or financial information, and former section 10(b) prohibited the EPA from disclosing those portions.

The 1972 amendments also allowed data submitters certain rights of compensation. Thus, the EPA was prohibited from using publicly available data it had received in support of one pesticide registration to support the registration of another pesticide unless the subsequent data user first offered to pay reasonable compensation to the original data submitter. Where possible, the level of compensation was to be negotiated by the original data submitter and the data user. Where agreement could not be reached, the EPA retained the power to set the level of compensation. The original data submitter, however, retained the right to appeal this determination to the federal district court.

Such a compensated use program had benefits for both the EPA and for registrants. It increased administrative efficiency by allowing the EPA to rely on already approved testing techniques and it benefited original data submitters by mandating compensation when their data was used by another registrant.

The 1978 amendments to FIFRA were enacted in response to certain problems which had arisen following the enactment of the 1972 revisions. Among these difficulties was the practice adopted by many data submitters of designating large portions of their data as "trade secret" material in order to avoid subsequent disclosure. Obviously, this tactic precluded the EPA's use of their data to support the registrations of competing pesticide manufacturers. As a result, the trade secret provisions both limited the EPA's efficient management of its registration process and undercut the compensation program envisioned by the drafters.

Pursuant to the 1978 amendments, all applicants are no longer required to make the extensive filings previously mandated. Rather, applicants must now file either "a full description of the tests made and the results thereof upon which the claims are based or, alternatively, a citation to data that appear in the public literature or that previously had been submitted to the Administrator..." 7 U.S.C. § 136a(c)(1)(D).

Moreover, although the original data submitter still retains certain proprietary rights in the data which it has submitted, those rights have been significantly altered. New section 3(c)(1)(D) no longer permits a data submitter to invoke trade secret protection. 7 U.S.C. § 136a(c)(1)(D). Rather, it divides all submitted data into three parts. Thus,

(1) with respect to pesticides containing active ingredients that are initially registered after September 30, 1978, the original data submitter is entitled to a period of exclusive use of that data for registration purposes for a period of 10 years;

(2) with respect to data submitted after December 31, 1969 and not subject to the exclusive use provisions set forth above, the EPA may use such data in its consideration of the registration applications

of applicants other than the original data submitter for a period of 15 years if the applicant has made an offer to compensate the original data submitter. The terms and amounts of compensation are to be set by the parties themselves. Should they fail to reach agreement on compensation, either party may initiate binding arbitration proceedings. The arbitrator's findings and determinations are not reviewable by the federal courts except for fraud, misrepresentation, or other misconduct; and

(3) with respect to data which is not subject to either the exclusive or the compensated use provision, the EPA may use data provided by an original data submitter in support of the registration of another applicant without the permission of the original submitter and without an offer of compensation being made.

In sum, the new program allows the developer of new "active ingredients" the exclusive use of its data for a period of ten years and compensated use for a period of five years following the termination of the exclusive use period. It allows registrants of data not qualifying for a period of exclusive use a fifteen-year period of compensated use. And finally, it provides for neither exclusive nor compensated use fifteen years after registration.

In addition to these new use provisions, the 1978 amendments impose new disclosure requirements on registrants. As I mentioned above, under the earlier law registrants were allowed to shield much of their filed data by designating portions thereof as trade secrets. The new section 10(d), 7 U.S.C. § 136h(d), "authorizes the public disclosure of all information concerning the objectives, methodology, results, or significance of any test performed on or with a pesticide, and of any residue, environmental chemistry, safety, toxicology, metabolism, and fish and wildlife data." Mobay Chemi-

cal Corp. v. Costle, supra, 517 F.Supp. at 260. Three significant classes of information, however, remain protected from disclosure "unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk, or injury to health or environment," 7 U.S.C. § 136h(d)(1):

(A) [information that] discloses manufacturing or quality control processes,

(B) [information that] discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately inert ingredient of a pesticide, or

(C) [information that] discloses the quantity of any deliberately added inert ingredient of a pesticide.

7 U.S.C. § 136h(d)(1). The use of data made available pursuant to this section for purposes of registration is governed by § 3(c)(1)(D), as set forth above.

In their complaint, plaintiffs attack two aspects of the 1978 FIFRA amendments. First, plaintiffs challenge new section 10 of FIFRA, 7 U.S.C. § 136h-the "disclosure" provision-which allows the EPA to disclose certain information to the public which had been submitted by plaintiffs prior to 1978 and which prior to that date had been insulated from public disclosure by the trade secret protections of the predecessor act. Plaintiffs contend that this disclosure provision is a retroactive deprivation of plaintiffs' property rights in their trade secret data in violation of due process of law. Second, plaintiffs challenge new section 3(c)(1)(D) of FIFRA, 7 U.S.C. § 136a(c)(1)(D)—the "use" provision-which permits the compensated use of plaintiffs' research data by other registrants to support their own federal pesticide registrations. Plaintiffs contend that the compensated use requirement, coupled with the particular arbitration remedy provided in the statute, is improper as an unconstitutional delegation of legislative

power to the private arbitrators and, alternatively, is a violation of the Constitution insofar as it deprives the judiciary of its traditional Article III function.

Defendant, by its cross-motion for summary judgment, contends that these sections withstand constitutional scrutiny. I first consider the "disclosure" provisions before turning to the "use' section.

#### The Disclosure Requirement<sup>1</sup>

As the preceding discussion indicates, prior to 1978. after submitting data in support of their products. pesticide registrants could then designate certain portions of their submissions as trade secret material. Once so designated, data was protected from disclosure by former section 10(b). The 1978 amendments, however, introduced a new program which strongly favors disclosure. Pursuant to new section 10(d), "all information concerning the objectives, methodology, results or significance of any test or experiment" submitted in support of a registration is subject to disclosure except insofar as that information may be protected by certain narrowly drawn exceptions. Thus, the new program affects all data in one of two ways. As to data submitted after the passage of the 1978 amendments, pesticide registrants are on notice that they are relinquishing their expectations to trade secret protection except as narrowly preserved by the statute itself. As to data submitted prior to 1978, the amendments operate more onerously. The expectation fostered by the pre-1978

¹ Plaintiffs have requested that the court postpone determination of this aspect of the motions because of the pendency of proposed legislation which would restructure the disclosure provisions in the statute. Insofar as that legislation does not appear to be substantially closer to enactment today than it was on the day that plaintiffs first made their request, that application is denied.

statute that data designated as trade secret material will be withheld from public disclosure no longer obtains. Only so much of the once-protected data as falls within the statutory exception remains protected from disclosure. The rest, even though it was once secret and even though it may have been submitted with the expectation that it would not be disclosed, is publicly available.

Plaintiffs challenge the retroactive effect of the 1978 amendments to section 10, 7 U.S.C. § 136h(d), and claim that the pre-1978 statute created the expectation that data designated "trade secret" would be preserved from disclosure and that this expectation fostered by statute constituted a "vested right." Plaintiffs further contend that the retroactive deprivation of this expectation divests them of their property without due process of law. They contend in addition, that this "retroactive application is so harsh and oppressive as to transgress the constitutional [due process] limitation." Welch v. Henry, 305 U.S. 134, 147 (1938).

Plaintiffs do not contest the new disclosure requirements as they apply to data submitted after the enactment of the 1978 amendments. As the Supreme Court commented in an analagous context:

[I]t is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold. The right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the state, in the exercise of its police power and in promotion of fair dealings, to require that the nature of the product be fairly set forth.

Corn Products Refining Co. v. Eddy, 249 U.S. 427, 431-32 (1919); see, also, National Fertilizers Ass'n v. Bradley, 301 U.S. 178 (1937). "Further, [l]egislative acts adjusting the burdens and benefits of economic life

come ... with a presumption of constitutionality, and ... the burden is on one complaining of a due process violation to establish that the legislature has acted in an arbitrary and irrational way." Usery v. Turner Elkhorn Mining Co., 428 U.S. 1, 15 (1976). Even legislation that has retroactive applicability "is not unlawful solely because it upsets otherwise settled expectation." 428 U.S. at 16. "The retroactive aspects [however] must meet the test of due process, and the justifications for the latter may not suffice for the former." 427 U.S. at 17. Thus, the constitutionality of the disclosure provisions must be judged by the standard due process test. If the challenged legislation bears a rational relation to the evil which it seeks to remedy. I may look no further. Williamson v. Lee Optical Co., 348 U.S. 487 (1955).

I conclude that the disclosure requirements embodied in section 10(d), 7 U.S.C. § 136h(d), are neither arbitrary nor irrational. FIFRA was revised in 1972 to accommodate the increasing public interest in the regulation of products which affect the environment with the interest of pesticide manufacturers in protecting costly research data from acquisitive competitors. FIFRA was amended again in 1978 to adjust the balance struck in 1972 when it became apparent that the statutory goal of granting the public access to the data from which they could conduct their own evaluations of new pesticides fell short of achievement by reason of registrants' ability to designate certain portions of their data as trade secrets. That the amendments could have been better drawn or if they upset settled expectations, is of no consequence. The Constitution does not require perfect economic regulation. It only requires that legislation not be arbitrary or irrational. The disclosure provisions meet that standard. Defendant's motion for summary judgment on this issue is therefore granted.

#### The Compensation-Arbitration Provisions<sup>2</sup>

Plaintiffs also challenge the compensation provisions of the amended statute. Section 3(c))1)(D), 7 U.S.C.

<sup>2</sup> Defendant contends that plaintiffs' challenge to the arbitration provisions in FIFRA are premature and that plaintiffs lack standing. I disagree and hold that they have presented a justiciable "cause or controversy."

In order to demonstrate standing, a claimant must show "injury in fact and a substantial likelihood that the judicial relief requested will prevent or redress the claimed injury." Duke Power Co. v. Caroline Environmental Study Group, 438 U.S. 59, 79. That second component may also be determined by resolving "whether the interest sought to be protected is arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." Assocation of Data Processing Service Organizations v. Camp, 397 U.S. 150 (1970).

In this instance, the inquiry therefore focuses on whether plaintiffs are suffering injury in fact by the operation of the arbitration requirements and whether "there is a 'substantial likelihood' that the relief requested will redress the injury claimed." Duke Power Co. v. Caroline Environmental Study Group, 438 U.S. at 75 n.2. Plaintiffs here would describe their alleged injury in terms of the statutory compulsion to participate in an arbitration procedure that is void ab initio as a matter of law and the deprivation thereby of any access to meaningful compensation for the use of their data by subsequent registrants. The Constitution requires only that the plaintiffs allege a "distinct and palpable injury" to satisfy the first component of the test. Warth v. Seldin, 422 U.S. 490, 501 (1975). The compulsion to arbitrate satisfies that component. Moreover, the second component is more easily satisfied. Where the Constitution requires only "a 'fairly traceable' causal connection betwen the claimed injury and the challenged conduct." Duke Power Co. v. Carolina Environmental Study Group, 438 U.S. at 72, quoting Arlington Heights v. Metropolitan Housing Development Corp., 429 U.S. 252, 21 (1977), plaintiffs' injuries here would be the direct product of the statutory plan. Plaintiffs are clearly within the zone of interest regulated by the use provisions.

Defendants also contend that plaintiffs' challenge to arbitration is not yet ripe for judicial review, i.e., whether an abstract or a concrete question is before the court. "The difference be§ 136a(c)(1)(D),3 the focus of plaintiffs' complaint, calls for the data user, in the first instance, to make a com-

tween an abstract question and a 'case or controversy' is one of degree, of course, and is not discernible by any precise test." Babbit v. United Farm Workers, 442 U.S. 289, 297 (1979). Here that question is best settled by inquiring into what profit there would be in the court's waiting for a later date. Defendant contends that this action will not be ripe for resolution until arbitration has produced results unfair to plaintiffs or at least until arbitration has been commenced. Nevertheless, it is not the results of any arbitration procedure that plaintiffs protest, or even the internal procedure thereof, rather it is the statutory compulsion to seek relief through arbitration to the exclusion of any other mechanism. That issue is clearly ripe for resolution.

3 Section 3(c)(1)(D) states, in pertinent part:

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes . . .

- (D) ... a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:
  - (i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not without the written permission of the original data submitted, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide:

Provided, That such permission shall not be required in the case of defensive data;

(ii) except as otherwise provided in subparagraph (D)(i) of this paragraph, with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintian in effect an existing registration, or for re-registration, the Administrator may, without the permission

pensation offer. If the data submitter does not accept that offer within 90 days and the parties have not agreed on a procedure to determine compensation, either the data user or the data submitter may then initiate binding arbitration proceedings. The statute, however, sets no guidelines or standards for the fixing of compensation. Moreover, it provides that 'the findings and determination of the arbitrator shall be final and conclusive" and that

of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data sumitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagrah. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determinaton of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct.

no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator....

Plaintiffs challenge the constitutionality of this provision on two grounds.4 First, they contend that the compensation-arbitration procedure is an unlawfully overbroad delegation because it (1) contains no standards for decision-making. (2) fails to set forth any system through which coherent standards can be developed, and (3) restricts sufficient access to judicial or administrative review. See Schecter Poultry Corp. v. United States, 295 U.S. 495 (1935); Panama Refining Co. v. Ryan, 293 U.S. 388 (1935). And second, they contend that the arbitration-compensation procedure impermissibly intrudes on areas of decision-making constitutionally entrusted to the judiciary. See Northern Pipeline Construction Co. v. Marathon Pipe Line Co., U.S. \_\_\_\_\_ 50 U.S.L.W. 4892 (June 28, 1982). While plaintiffs appear correct in their contention that this is a standardless delegation of powers, what is dispositive here is the fact that the proposed arbitration procedure commits to arbitrators the power to resolve valuation issues utterly without judicial review. This

<sup>4 &</sup>quot;Courts confronted with the questions whether there is a property right in submitted testing data and whether, if there is, the statutory program constitues a "taking" have reached differing conclusions. Compare Monsanto Company v. Acting Administrator, No. 79-366 C. (E.D. Mo. April 19, 1983, with Mobay Chemical Corp. v. Gorsuch, 682 F.2d 419 (3rd Cir. 1982), affirming in part, Mobay Chemical Corp. v. Costle, 517 F.Supp. 254 (W.D.Pa. 1981), with Petrolite Corp. v. EPA, 519 F.Supp. 996 (D.D.C. 1981); cf., Union Carbide Agricultural Products Co., Inc. v. Costle, 632 F.2d 1014 (2d Cir. 1980).

absolute assignment of power to arbitrators is an impermissible intrusion on the judiciary.

In Northern Pipeline, the Supreme Court held that although the Congress possesses substantial discretion to create substantive federal rights and to tailor the manner in which they may be adjudicated, including the assignment to an adjunct of some functions historically performed by judges . . . [,] the functions of the adjunct must be limited in such a way that 'the essential attributes' of judicial power are retained in the Art. III court." 50 U.S.L.W. at 4900. There can be no question that on its very face § 3(c)(1)(D) fails to abide by this limitation. Accord, Monsanto Company v. Acting Administrator, No. 79-366C (E.D. Mo. April 19, 1983).

The use-compensation system utterly deprives the federal courts of any meaningful role in ensuring the provision of fair compenstion to data submitters. The courts play no role in fact-finding. More importantly, however, they are barred from considering any matters of law arising from the substantive issues in dispute in an arbitration proceeding. Rather, their powers are limited to review for "fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator." This leaves the courts with no power to make any "informed, final determination" of a data submitter's right to compensation. Such an assignment of powers to arbitrators cannot be sustained in the face of Article III.

Submit order on notice effectuating the foregoing.

/8/

R. OWEN
United States District Judge

Dated: July 28, 1983 New York, N.Y.

#### APPENDIX B

# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

76 Civ. 2913 (RO)

Union Carbide Agricultural Products Co., Inc., ET Al., Plaintiffs,

against

WILIAM D. RUCKLESHAUS, AS ADMINISTRATOR OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, ET AL., DEFENDANTS

November 29, 1983

#### JUDGMENT AND ORDER

OWEN, District Judge

Upon consideration of the cross-motions of the parties for summary judgment and the record in this case, judgment is entered as follows:

- 1. It is hereby ordered, adjudged and decreed that the provisions for the determination of compensation of section 3 (c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended by the Federal Pesticide Act of 1978, 7 U.S.C. § 136a(c)(1)(D) (not including the provisions of section 3(c)(1)(D)(i)), are unconstitutional as a violation of Article III of the Constitution.
- 2. It is further ordered, adjudged and decreed that defendant William D. Ruckelshaus, as Administrator of the United States Environmental Protection Agency, and his officers, agents, employees and representatives, are hereby permanently enjoined from permitting or implementing any use of data where the submitter's compensation is to be determined under the said

section 3(c)(1)(d), *supra*; provided, however, that notwithstanding the foregoing, any submitter may file a consent to the use of its data in support of a registration or amendment, in which case such registration or amendment shall not be subject to this injunction.

- 3. It is therefore ordered that to the foregoing extent, plaintiffs' motion for summary judgment is granted.
- 4. It is further ordered that with respect to plaintiffs' claim as to section 10 of the Federal Insecticide, Fungicide and Rodenticide Act, summary judgment is hereby entered in favor of the defendants and Count I of the amended complaint is dismissed with prejudice.
  - 5. Each party is to bear its own costs.

/S/					
R. OWEN					
United	States	District	Judge		

Dated: November 29, 1983 New York, N.Y.

Judgment Entered 11/30/83/s/

RAYMOND F. BURGHARDT Clerk

#### APPENDIX C

#### UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

76 Civ. 2913 (RO)

UNION CARBIDE AGRICULTURAL PRODUCTS Co., ET AL., PLAINTIFFS,

against

WILIAM RUCKLESHAUS, ADMINISTRATOR UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, ET ANO., DEFENDANTS

[Filed: Dec 21, 1983]

#### NOTICE OF APPEAL

PLEASE TAKE NOTICE that, pursuant to 28 U.S.C. § 1252, defendants William D. Ruckelshaus, Administrator of the United States Environmental Protection Agency, and the United States Environmental Protection Agency hereby appeal to the United States Supreme Court from so much of a judgment entered in this Court on November 29, 1983, as declared a portion of section 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136a(3)(c)(1)(D), unconstitutional and enjoined its enforcement.

RUDOLPH W. GIULIANI United States Attorney for the Southern District of New York, Attorney for Defendants

Dated: New York, New York December 21, 1983 By: /s/
MICHAEL H. DOLINGER
Assistant United States Attorney
One St. Andrew's Plaza
New York, New York
Tele. No.: (212) 791-0052

#### APPENDIX D

# CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article III, Section 1, of the Constitution provides in pertinent part:

The judicial power of the United States shall be vested in one Supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish.

The relevant provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. (& Supp. V) 136 et seq., as amended in 1978, provide:

#### § 136a(c). Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(D) except as otherwise provided in subsection (c)(2)(D) of this section, if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment

adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitted, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide: *Provided*, That such permission shall not be required in the case of defensive data;

(ii) except as otherwise provided in subparagraph (D)(i) of this paragraph, with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit. or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by aggreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the orginal data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount

and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or cancelled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation:

(iii) after expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under subparagraphs (D)(i) and (D)(ii) of this paragraph, the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item

of data;

(E) the complete formula of the pesticide; and

(F) a request that the pesticide be classified for general use, for restricted use, or for both.